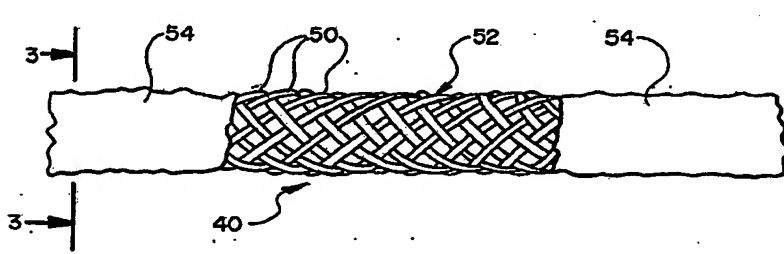




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 : A61M 29/02	A1	(11) International Publication Number: WO 93/20881 (43) International Publication Date: 28 October 1993 (28.10.93)
(21) International Application Number: PCT/US93/03352 (22) International Filing Date: 9 April 1993 (09.04.93) (30) Priority data: 07/867,164 9 April 1992 (09.04.92) US (71) Applicant (for all designated States except US): SCIMED LIFE SYSTEMS, INC. [US/US]; 6655 Wedgewood Road, Maple Grove, MN 55311-3648 (US). (72) Inventors; and (75) Inventors/Applicants (for US only) : PRAY, James, R. [US/US]; 8508 - 49th Avenue North, New Hope, MN 55427 (US). CORNELIUS, Richard, G. [US/US]; 1129 Welcome Circle, Golden Valley, MN 55422 (US). ARNEY, Michelle [US/US]; 1811 - 1st Avenue South, Apt. 1, Minneapolis, MN 55403 (US).		(74) Agents: STEINKRAUS, Walter, J. et al.; Vidas, Arrett & Steinkraus, 1540 Minneapolis Centre, 920 Second Avenue South, Minneapolis, MN 55402-4014 (US). (81) Designated States: CA, JP, US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i>
(54) Title: DILATATION CATHETER WITH POLYIMIDE-ENCASED STAINLESS STEEL BRAID PROXIMAL SHAFT		
		
(57) Abstract <p>A dilatation balloon catheter (10) includes a shaft (12) having a proximal outer tube section and a distal outer tube section. The proximal outer tube section (40) is formed from a tubular braid of a stainless steel member, which is encased in a polymer material such as polyimide. The pick count of the braid may be increased along the proximal outer tube section toward its distal end in order to increase flexibility. The distal outer tube section (42) is a tube made of a polymer material, such as a high density polyethylene.</p>		

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	FR	France	MR	Mauritania
AU	Australia	GA	Gabon	MW	Malawi
BB	Barbados	GB	United Kingdom	NL	Netherlands
BE	Belgium	GN	Guinea	NO	Norway
BF	Burkina Faso	GR	Greece	NZ	New Zealand
BG	Bulgaria	HU	Hungary	PL	Poland
BJ	Benin	IE	Ireland	PT	Portugal
BR	Brazil	IT	Italy	RO	Romania
CA	Canada	JP	Japan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo	KR	Republic of Korea	SE	Sweden
CH	Switzerland	KZ	Kazakhstan	SK	Slovak Republic
CI	Côte d'Ivoire	LI	Liechtenstein	SN	Senegal
CM	Cameroon	LK	Sri Lanka	SU	Soviet Union
CS	Czechoslovakia	LU	Luxembourg	TD	Chad
CZ	Czech Republic	MC	Monaco	TG	Togo
DE	Germany	MG	Madagascar	UA	Ukraine
DK	Denmark	ML	Mali	US	United States of America
ES	Spain	MN	Mongolia	VN	Viet Nam
FI	Finland				

**DILATATION CATHETER WITH POLYIMIDE-ENCASED
STAINLESS STEEL BRAID PROXIMAL SHAFT**

BACKGROUND OF THE INVENTION

5 The present invention relates to a dilatation catheter for use in angioplasty. Angioplasty has gained wide acceptance as an efficient and effective method of opening stenoses in the vascular system. In the most widely used form of angioplasty, a dilatation balloon catheter is guided through the vascular system until a balloon, which is mounted at the distal end of the catheter shaft, is positioned
10 across the stenosis. The balloon is then inflated to open the artery and reestablish acceptable blood flow.

 Dilatation catheters can generally be divided into those which are fed over a guide wire (i.e., "over the-wire" catheters) and those catheters which serve as their own guide wire (i.e., "fixed-wire" catheters). Both types of catheters have
15 advantages and disadvantages.

 Innerless dilatation balloon catheters have been developed in an attempt to obtain some of the advantages of a fixed-wire catheter while still retaining the advantages of an over-the-wire catheter. These innerless catheters feature a shaft having a single lumen which acts as both an inflation lumen and a guide wire lumen.
20 A lumen extension extends through the balloon, which is mounted on the distal end of the shaft. The shaft lumen is in fluid communication with the interior of the balloon. The guide wire extends through the shaft lumen, the lumen extension and out the distal end of the balloon.

 Examples of innerless dilatation balloon catheters are shown in U.S.
25 Patents 5,032,113 and 5,035,705 by Matthew M. Burns.

 When used in percutaneous transluminal coronary angioplasty (PTCA), the dilatation catheter is typically advanced through a guide catheter to the aorta. Using fluoroscopy, the physician manipulates the catheter until the balloon is located across the stenosis. This may involve the use of a guide wire over which the
30 catheter is moved. Alternatively, the catheter may act as its own guide wire, depending upon the particular design. The manipulation of the dilatation catheter through the guide catheter and through the coronary arteries to the stenosis requires

the dilatation catheter to have a number of different, sometimes conflicting, characteristics.

For example, a successful dilatation catheter must offer flexibility so that the catheter can maneuver through tight curvatures of the vascular system. A dilatation catheter also must allow the physician to transmit longitudinal force along the dilation catheter from its proximal end to its distal end so the catheter can be pushed through the guide catheter and arteries and across the stenosis. This characteristic is referred to as pushability. Typically, the outer dimensions of all parts of the dilatation catheter, including particularly the shaft, should be minimized. Friction between the dilatation catheter, the guide catheter and the guide wire, respectively, should also be minimized.

Prior dilatation catheters typically reflected trade-offs between these and other characteristics. For example, catheters having shafts with sections of different materials have been used in order to provide greater flexibility at the distal end of the catheter. Thin wall materials such as stainless steel hypo tubing and polyimide tubing have been used for proximal sections of dilatation catheter shafts in order to reduce the outer diameter and wall thickness of the catheter shaft.

SUMMARY OF THE INVENTION

The present invention is an improved dilatation catheter having a shaft with a proximal section formed by a composite polymer/stainless steel braid tube, and a distal section formed by a flexible polymer tube. The distal section, which is preferably a polyethylene tube, has greater flexibility than the proximal section. In one embodiment, the shaft of the present invention forms the outer tube of an over-the wire balloon catheter. In an alternative embodiment, the shaft of the present invention functions as a single-lumen shaft for either a fixed-wire balloon catheter or an innerless catheter.

In preferred embodiments of the present invention, the composite tube which forms the proximal section of the shaft has a wall thickness at its thickest points of about 0.079 mm (0.0031 inches) to about 0.089 mm (0.0035 inches). The stainless steel braid is formed by multiple strands of stainless steel member, such as a ribbon or a wire, which are woven in a "clothing weave" and are encased in a polymer matrix comprising polyimide. The stainless steel ribbon preferably has a thickness of about 0.018 mm (0.0007 inches) to about 0.025 mm (0.0010 inches) and

width of about 0.071 mm (0.0028 inches) to about 0.135 mm (0.0053 inches) and the stainless steel wire preferably has a diameter in the range of 0.025 mm (0.001 inches) to 0.038mm (0.0015 inches).

5 In a further embodiment, the braid weave of the proximal section of the shaft has a varying pick count, increasing in the distal direction, thereby providing an increasing flexibility as one moves in the distal direction. This feature allows for increased pushability at the proximal end of the shaft while reducing the difference in flexibility between the proximal and distal portions of the shaft at their junction.

10

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a partial sectional view of a first embodiment of the dilatation catheter of the present invention, with the distal portion of the catheter shown in a larger scale than the proximal portions.

15 Figure 2 is a front view, with portions broken away, showing the outer surface of the composite tube which forms the proximal shaft section of the dilatation catheter of Figure 1.

Figure 3 is a cross-sectional view of the composite tube taken on line 3-3 of Figure 2.

20 Figure 4 is a partial sectional view of a second embodiment of the present invention as applied in an innerless dilatation catheter.

Figure 5 is a sectional view showing in further detail the distal portion of the innerless dilatation catheter of Figure 4.

Figure 6A is a sectional view of the innerless dilatation catheter taken on line 6-6 of Figure 5 with an open valve.

25 Figure 6B is a sectional view of the innerless dilatation catheter taken on line 6-6 of Figure 5 with a closed valve.

Figure 7 is a sectional view showing another embodiment of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

30

Dilatation catheter 10 shown in Figure 1 is an over-the-wire balloon catheter which includes shaft 12, manifold 14, and inflatable balloon 16. Manifold 14, which includes thru port 18 and balloon inflation port 20, is connected to the proximal end of shaft 12. Balloon 16 is mounted at the distal end of shaft 12.

Shaft 12 includes outer tube 22 and inner tube 24. Inflation lumen 26, which permits fluid communication between inflation port 20 of manifold 14 and the interior of balloon 16, is defined between the inner wall of outer tube 22 and the outer wall of inner tube 24.

5 Guide wire lumen 28 extends through the center of inner tube 24. Guide wire lumen 28 provides a path for a guide wire (not shown) from thru port 18 to the distal end of dilatation catheter 10.

Inflatable balloon 16 includes proximal balloon waist 30, intermediate inflatable portion 32, and distal end portion 34. Balloon waist 30 is connected to the
10 distal end of outer tube 22, and distal end portion 34 of balloon 16 is connected to the distal end of inner tube 24.

Located within balloon 16 on inner tube 24 is marker band 36. In a preferred embodiment, marker band 36 is a radiopaque material, such as a platinum alloy.

15 Inner tube 24 is a unitary polyethylene tube having proximal section 24A and distal section 24B. Inner tube 24 is formed by necking down the polyethylene tube so that distal section 24B has a smaller outer diameter than proximal section 24A.

Outer tube 22 is formed by two different tube materials. Proximal
20 section 40 of outer tube 22 is a composite tube formed by a stainless steel braid which is encased in a polymer matrix comprising polyimide. In one preferred embodiment, proximal section 40 has a length of about 106.7-109.2 cm (42 to 43 inches), an outer diameter of between about 0.932 mm (0.0367 inches) and about 0.958 mm (0.0377 inches), and a wall thickness of about 0.079 mm (0.0031 inches).

25 In one embodiment, distal section 42 of outer tube 22 is a polymer tube, such as high density polyethylene tube, which has its proximal end bonded to the distal end of proximal section 40 and has its distal end connected to balloon waist 30. Distal section 42 of outer tube 22 has a first segment 42A and a second, smaller-diameter section 42B. In a preferred embodiment, the overall length of distal
30 section 42 is between about 29.2-31.8 cm (11.5 and 12.5 inches), with first segment 42A having a length of about 10.2 cm (4 inches) and second segment 42B having a length of about 20.3 cm (8 inches).

The outer diameter of section 42B varies depending upon the size of the inflated outer diameter of balloon 16. For smaller balloon sizes (i.e., inflated diameters of 1.5 and 2.0 millimeters), the outer diameter of section 42B is preferably about 0.762 mm (0.030 inches) to about 0.788 mm (0.031 inches). For larger
5 balloon sizes (i.e., inflated diameters of 2.5 to 3.5 millimeters), the outer diameter of section 42B is about 0.826 mm (0.0325 inches) to about 0.901 mm (0.0335 inches).

Outer tube 22 is flexible along its entire length. Distal section 42 of outer tube 22, however, has greater flexibility than proximal section 40. This provides the needed flexibility to allow catheter 10 to conform to the curvatures of
10 the patient's vascular system. The composite polyimide-encased stainless steel braid tube which forms proximal section 40 offers enhanced pushability and a relatively small wall thickness, so that the outer diameter of outer tube 22 can be kept to a minimum.

Figures 2 and 3 illustrate in greater detail the composite
15 polyimide-encased stainless steel braid tube which forms proximal section 40 used in the catheter of the present invention. Individual strands of stainless steel ribbon 50 are interwoven as shown in Figure 2 to form a tubular braid 52. Polymer matrix material 54 encases tubular braid 52. The polymer matrix material 54 suitably comprises polyimide and is thick enough to provide structural integrity to tube 40, so
20 that proximal tube section 40 can contain fluid without leaking. Portions of individual strands of tubular braid 52 on the inner surface thereof may be exposed so long as they are effectively entrained in the polyimide matrix and the tube does not leak. The polymer matrix material 54 which encases braid 52 is thin enough so that it conforms generally to the outer surface of woven braid 52. This is illustrated in
25 Figures 2 and 3, which show the relatively textured outer surface of proximal tube section 40. This exterior surface texture or roughness of proximal tube section 40 is a significant advantage. It reduces the points of contact (and drag) between proximal tube section 40 and the inner surface of the guide catheter (not shown) through which dilatation catheter 10 must be advanced. The rough surface of the composite
30 polyimide-encased stainless steel tube of proximal section 40 of outer tube 22 exhibits significantly less drag in the guide catheter than smooth-surfaced polyimide proximal tube sections of similar dilatation catheters.

In a preferred embodiment of the present invention, individual strands 50 are 304 spring temper stainless steel ribbon having a thickness of about 0.018 mm (0.0007 inches) and a width of about 0.005 inches). Sixteen strands are woven together in a clothing weave to form tubular braid 52, with the weave being about
5 17.8 - 35.4 picks/cm (45 to 90 picks/inch). The composite wall thickness of proximal tube section 40 (i.e., braid 52 plus polyimide material 54 at the thickest points) is between about 0.064 and 0.102 mm (0.0025 and 0.0040 inches), and preferably is about 0.079 mm (0.0031 inches) to about 0.089 mm (0.0035 inches). The stainless steel braid/polyimide composite tube described is manufactured by HV
10 Technologies of Trenton, Georgia.

Thinner walled proximal sections of a catheter shaft have been made of stainless steel hypo tubing or polyimide tubing in the past. The combination of composite proximal tube section 40 and the more flexible polyethylene distal tube section 42 of the present invention, however, offers a number of significant
15 advantages.

First, the drag coefficient of the textured exterior surface of proximal tube section 40 is significantly less than smooth-surfaced polyimide proximal tube sections of similar dilatation catheters. Therefore, the proximal tube section 40 of the present invention advances more easily through the guide catheter.

20 Second, the present invention offers improved pushability when compared to catheters using a thin wall polyimide tube for the proximal section.

Third, the catheter of the present invention exhibits less tendency for kinking during preparation for a dilatation procedure or during a dilatation procedure than prior art catheters which use high strength materials such as stainless steel and polyimide at the proximal section. This is because the stiffness transition between
25 sections 40 and 42 is less abrupt than the stiffness transition between a proximal stainless steel hypo tube and a more flexible polymer distal section. In the case of polyimide proximal sections, the kinking tendency exists because the thin walls have brittle characteristics.

30 Finally, composite proximal tube section 40 used in catheter 10 of the present invention is more flexible than a stainless steel hypo tube proximal outer tube section. As a result, catheter 10 of the present invention is easier to handle when removing the catheter from its packaging and preparing it for use.

Figure 4 is a partial sectional view of a second embodiment of the present invention functioning as an innerless dilatation catheter. Figure 4 shows dilatation catheter 110 and guide wire 112, which are used to perform angioplasty procedures. Dilatation catheter 110 includes manifold 114, proximal shaft 116, distal shaft 118, strain relief 120, balloon 122, proximal lumen extension 124, distal lumen extension 126, marker band 128, and stretch responsive valve 130.

Manifold 114 is located at the proximal end of the dilatation catheter 110. Manifold 114 includes thru port 132 (through which guide wire 112 passes), balloon port 134 (through which inflation fluid is provided to and withdrawn from balloon 122) and manifold valve 135.

Proximal shaft 116 is a single lumen tube having its proximal end 136 connected to manifold 114, and its distal end 138 connected to distal shaft 118. Shaft lumen 140 extends from proximal end 136 to distal end 138 of shaft 116. Lumen 140 is in fluid communication with balloon port 134 and thru port 132 of manifold 114, and also provides a passage for guide wire 112.

Proximal shaft 116 is preferably a polyimide/stainless steel braid composite tube from HV Technologies of Trenton, Georgia with an inner diameter of about 0.673 mm (0.0265 inches) and an outer diameter of about 0.838 mm (0.033 inches). The length of proximal shaft 116 is about 103 centimeters.

Strain relief 120 is a 0.025 mm (0.001 inch) by 0.102 mm (0.004 inch) stainless steel ribbon which is wrapped around proximal shaft 116 and distal shaft 118 and covered by a heat-shrunk polymer sheath. Strain relief 120 has an outer diameter of about 0.965 mm (0.038 inches) and a length of about 2.5 centimeters.

Distal shaft 118 includes proximal neck section 142, shaft sections 144 and 146, bond neck section 148, and valve neck section 150. Proximal neck section 142 is bonded to distal end 138 of proximal shaft 116. In a preferred embodiment of the present invention, distal shaft 118 and distal lumen extension 126 are formed of high density polyethylene tubing and are formed as one piece by a series of necking operations. Distal lumen extension 126 is subsequently severed from valve neck section 150 to create the gap for valve 130.

Strain relief 120, which is preferably a wrapped stainless steel ribbon covered by a thin heat shrunk polymer sleeve, fits over the bond between distal portion of shaft 116 and the proximal portion of shaft 118. Strain relief 120 provides

additional strength at the bond between shafts 116 and 118, particularly when tension is applied to the bond. In an alternative embodiment, the bond between shafts 116 and 118 is strong enough to avoid the need for strain relief 120.

5 Shaft section 144 of distal shaft 118 has an outer diameter which is equal to or slightly less than the outer diameter of proximal shaft 116. In the embodiment shown in Figure 4, shaft section 146 is positioned intermediate to shaft section 144 and bond neck section 148. Shaft section 146 has a reduced outer and inner diameter with respect to section 144 and, in the preferred embodiment, has a greater flexibility than proximal shaft 116 and shaft section 144 of distal shaft 118.

10 Bond neck section 148 has a reduced outer and inner diameter with respect to shaft section 146. Valve neck section 150 has a reduced outer and inner diameter with respect to bond neck section 148. Bond neck section 148 and valve neck section 150 together form proximal lumen extension 124. Distal shaft 118 has a lumen 152 which is aligned with lumen 140 of proximal shaft 116.

15 Balloon 122 includes proximal balloon waist 154, main balloon body 156, and distal end section 158. Proximal balloon waist 154 is bonded to bond neck section 148 by adhesive 160. Similarly, distal end section 158 of balloon 122 is bonded by adhesive 162 to the distal end of distal lumen extension 126.

20 As shown in Figure 4, guide wire 112 extends from thru port 132 of manifold 114, through shaft lumens 140 and 152, through proximal lumen extension 124 (formed by bond neck section 148 and valve neck section 150), through stretch responsive valve 130, through distal lumen extension 126 and out the distal end 158 of balloon 122 of catheter 110.

25 Inflation of balloon 122 is effected by passing fluid (not shown) through lumens 140 and 152 and vent holes 164 and 165 in proximal lumen extension 124. The fluid flow resistance through vent holes 164 and 165 is preferably less than the fluid resistance between guide wire 112 and the remainder of the lumen extension distal to vent holes 164 and 165. In this way, it is possible to supply inflation fluid under pressure to the interior of balloon 122 through the same
30 lumen 140, 152 used by guide wire 112.

Referring to Figures 4 and 5, the present invention further limits the flow of fluid in either direction between lumen 152 and the distal end of catheter 110 by the action of stretch responsive valve 130 during balloon inflation. The present

invention takes advantage of a characteristic of certain balloon material: a longitudinal compliance of balloon 122. In other words, as balloon 122 is inflated, it tends to elongate. This causes the distance between proximal balloon waist 154 and distal end section 158 to increase as balloon 122 is inflated. Because proximal
5 balloon waist 154 is secured by adhesive 160 to bond neck section 148, and distal end section 158 is attached by adhesive 162 to a distal end 126A of distal lumen extension 126, a proximal end 126B of distal lumen extension 126 tends to move away from valve neck section 150 as the balloon 122 is inflated.

As best shown in Figure 5, stretch responsive valve 130 is preferably a
10 stretchable tube having a proximal section 166 attached to valve neck section 150, and a distal section 168 attached to proximal end 126B of distal lumen extension 126. Intermediate section 170 of valve 130 is located in the gap between valve neck 150 and distal lumen extension 126.

Elongation of balloon 122 due to its inflation causes valve 130 to
15 stretch. As valve 130 is stretched, the length of intermediate section 170 increases and the inner diameter of intermediate section 170 correspondingly decreases. Consequently, stretching valve 130 effectively decreases the inner diameter of a portion of the lumen extension. Preferably the amount of stretching of balloon 122, and the dimensions of valve 130 and guide wire 112 are determined while balloon
20 122 is inflated to pressures in its working range (approximately 0 to 18 atmospheres); the inner wall of valve 130 approximates the outer surface of guide wire 112 and substantially blocks fluid flow in either direction through valve 130.

At low inflation pressures of balloon 122, valve 130 stretches sufficiently to effect the constricting action of valve 130 and restrict fluid flow
25 between lumen 152 and distal end 126A of distal lumen extension 126.

To achieve this valve action, proximal lumen extension 124 (formed by bond neck section 148 and valve neck section 150) and distal lumen extension 126 must be sufficiently rigid to transmit force to valve 130. In a preferred embodiment of the present invention, the amount of elongation of balloon 122 in its
30 working range is approximately 0 to 10 millimeters.

In a preferred embodiment of the present invention, balloon 122 is a polyolefin balloon material, such as Surlyn 8527 from Dupont, which exhibits longitudinal compliance (stretching) during inflation. Proximal balloon waist 154 has

an inner diameter of about 0.665 to 0.711 mm (0.0262 to 0.0280 inches) and an outer diameter of about 0.838 to 1.067 mm (0.033 to 0.042 inches) maximum depending on the inflated outer diameter of balloon 122. Distal end section 158 of balloon 122 has an inner diameter of about 0.521 to 0.584 mm (0.0205 to 0.023 inches). The
5 overall length of balloon 122 is typically between 1 to 4 centimeters. Proximal balloon waist 154 has a length of about 8 millimeters, and distal end section 158 has a length of about 3 millimeters.

In a preferred embodiment of the present invention, distal shaft 118 and distal lumen extension 126 are formed of high density polyethylene tubing and
10 are formed as one piece by a series of necking operations. Distal lumen extension 126 is subsequently severed from valve neck section 150 to create the gap for valve 130.

In the preferred embodiment, proximal neck section 142 has a length of about 4 millimeters, an inside diameter of about 0.533 mm (0.021 inches), and an
15 outer diameter of about 0.635 mm (0.025 inches). Shaft section 144 has a length of about 9 centimeters, and an inner diameter of about 0.622 to 0.666 mm (0.0245 to 0.0270 inches), and an outer diameter of about 0.813 mm (0.032 inches).

Shaft section 146 has a length of about 23 centimeters, an inner diameter of about 0.508 to 0.686 mm (0.020 to 0.027 inches) and an outer diameter
20 of about 0.635 to 0.838 mm (0.025 to 0.033 inches). Bond neck section 148 has a length of about 10 millimeters, an outer diameter of about 0.640 to 0.653 mm (0.0252 to 0.0257 inches) and an inner diameter of about .0508 to 0.533 mm (0.020 to 0.021 inches). Vent holes 164 and 165 are round holes about 0.178 to 0.254 mm (0.007 to 0.010 inches) in diameter. Vent hole 164 is located about 9.5 millimeters
25 distal to shaft section 146. Vent hole 165 is located about 8.5 millimeters distal to shaft section 146. Vent hole 164 is positioned 180 degrees from vent hole 65 around the circumference of bond neck section 148, as illustrated in Figures 4 and 5.

Valve neck section 150 and distal lumen extension 126 have inner diameters of about 0.381 to 0.406 mm (0.015 to 0.016 inches) and outer diameters of
30 about 0.470 to 0.508 mm (0.0185 to 0.020 inches). Valve neck section 150 has a length of about 2.5 millimeters, while distal lumen extension 126 has a length which depends on the size and length of balloon 122.

The reduced diameter sections of dilatation catheter 110, such as valve neck section 150 and distal lumen extension 126, have become oriented molecularly as a result of the necking down of the high density polyethylene tubing. This provides the additional rigidity in the axial direction necessary to transmit force from proximal balloon waist 154 and distal end section 158 of balloon 122 to valve 130.

In this preferred embodiment, valve 130 is a tube made of a polyurethane, such as Pellethane 2352-70A, or Tecothane TT-1075A from Thermedics, with an inner diameter of about 0.368 to 0.381 mm (0.0145 to 0.0150 inches) and a maximum outer diameter of about 0.508 mm (0.020 inches). Valve 130 is soaked in alcohol and then stretched over valve neck section 150 and proximal end 126B of distal lumen extension 126. In one embodiment, valve neck section 150 and proximal end 126B of distal lumen extension each include a circumferential ridge (not shown), which aids in the retention of valve 130. Proximal section 166 and distal section 168 of valve 130 are about 1.5 to 3.0 millimeters in length, while intermediate section 170 is about 1 to 5 millimeters in length in its unstretched state. The total elongation of balloon 122 is about 0 to 10 millimeters.

Marker band 128 is a band of radiopaque metal located on distal lumen extension 126 near proximal end 126B such that marker band 128 is positioned approximately in the center of balloon 122. Marker band 128 has an inner diameter of about 0.521 to 0.533 mm (0.0205 to 0.0210 inches) and a wall thickness of about 0.048 to .051 mm (0.0019 to 0.0020 inches).

Guide wire 112, used in conjunction with catheter 110, has an overall length of about 175 centimeters. The outer diameter of guide wire 112 is about 0.356 mm (0.014 inches) over the length of the body. The inner surfaces of proximal lumen extension 124, distal lumen extension 126 and valve 130 must be large enough to permit free passage of guide wire 112 when balloon 122 is not inflated, yet be in close enough proximity to guide wire 112 to allow valve 130 to create the desired seal around wire 112 while balloon 122 is in an inflated state.

As shown in Figure 6A, in an unstretched state, the inner surface 172 of valve 130 is not in contiguous contact with guide wire 112, thereby permitting free passage of guide wire 112 through valve 130. The close proximity of guide wire 112 with inner surface 172 of valve 130 and the inner surfaces of valve neck section 150 and distal lumen extension 126 (not shown) are such that the inflation

fluid distal to vent holes 164 and 165 experiences greater flow resistance with respect to the fluid flow resistance through vent holes 164 and 165 shown in Figure 5. This yields minimal fluid leakage out the distal end of innerless dilatation catheter 110 while balloon 122 is inflating and valve 130 is constricting around guide wire 112 to
5 block fluid flow.

Figure 6B demonstrates valve 130 in a stretched state where the stretching decreases the inner and outer diameter of valve 130 thereby bringing inner surface 172 of valve 130 in close proximity to guide wire 112 and substantially blocking fluid flow through distal lumen extension 126 (not shown).

10 Other constructions of valve 130 are also possible within the scope of the present invention. For example, the location of valve 130 within balloon 122 may be varied, and the dimensions of valve 130 can be changed. Also, valve 130 could be positioned within the distal portion of shaft 118.

A sectional view of another embodiment of the present invention is
15 shown in Figure 7. Distal end of catheter 200 with balloon 202 is shown with proximal lumen extension 204 connected to and extending from the distal end of shaft 206. Vent holes 208 and 210 are positioned on proximal lumen extension 204 to permit fluid communication between lumen 212 of shaft 206 and balloon 202. Unlike the embodiment shown in Figure 5, however, the proximal lumen extension
20 204 extends to approximately an intermediate location within balloon 202. Marker band 214 is affixed near the distal end of proximal lumen extension 204.

The proximal end of valve 216 is connected to the distal end of proximal lumen extension 204, and the distal end of valve 216 is bonded to distal balloon waist 218. Valve 216 therefore defines the distal lumen extension 126 of
25 Figure 5. Like valve 130 of Figure 5, valve 216 is axially compliant when tension is applied during balloon inflation. Other constructions of valve 216 are also possible. For example, valve 216 and distal lumen extension 204 can be incorporated into a single elastic tubular member which has compression strength in the axial direction and flexibility in tension while retaining sufficient elasticity to allow the tubular
30 member to stretch and create a seal around guide wire 220 as balloon 202 inflates and elongates.

Guide wire 220 extends from lumen 212 of shaft 206 through proximal lumen extension 204 and valve 216 (shown in its unstretched state) and out

the distal end of catheter 200. As balloon 202 is inflated and elongated, tension is applied to valve 216 thereby causing valve 216 to stretch and reduce its inner and outer diameter along essentially the entire length of valve 216. The inner diameter of a substantial length of valve 216 in a stretched state approximates the outer
5 diameter of guide wire 220 while balloon 202 is inflated. This causes an effective obstruction of lumen 212 which essentially suppresses the flow of inflation fluid out the distal end of catheter 200 while balloon 202 is inflated.

Other constructions of innerless catheter 110 of Figure 4 are also possible within the scope of the present invention. For example, catheter 110 can
10 also accompany guide wires of different outer diameters (e.g., 0.254, 0.457 and 0.889 mm (0.010, 0.018, and 0.035 inches)) and balloons of different inflated diameters. The components of catheter 110 are dimensionally scaled accordingly.

Although the present invention has been described with reference to preferred embodiments, workers skilled in the art will recognize that changes may be
15 made in form and detail without departing from the spirit and scope of the invention. For example, for different size catheters, the dimensions of the various components will vary. In the case of the proximal outer tube section 140, outer diameters preferably range from about 0.762 mm (0.0300 inches) to about 1.32 mm (0.0520 inches) maximum. Lengths range from about 81.3 to 118.8 cm (32 to 46 inches).
20 Wall thicknesses at points of maximum thickness are about 0.064 to about 0.102 mm (0.0025 to about 0.0040 inches). The braid strands are in the range of about 0.008 mm (0.0003 inches) to about 0.038 mm (0.0015 inches) in thickness and in the range of about 0.038 to about 0.178 mm (0.0015 to about 0.007 inches) width. The weave is preferably in the range of 17.7 to 35.4 picks per cm (45 to 90 picks per inch).

25 In a further preferred embodiment of the invention, the flexibility of the braided proximal portion is variable, becoming progressively less stiff as one moves from the proximal to the distal end thereof. There are several ways to achieve increased flexibility along the catheter shaft. These methods include grinding, etching, secondary polymer coating and braid pick variation. Of these, pick
30 count variation is much preferred because it does not require additional process steps and provides a much greater variation in flexibility over the length of the shaft. Specifically, it has been found that as pick count increases the stiffness decreases.

Suitably the stiffness of the proximal outer tube section is in the range of 110-130 gm/cm, typically 117-130 gm/cm, at the proximal end thereof and is in the range of 15-41 gm/cm, typically 21-41 gm/cm, at the distal end thereof using a 1.27 cm segment for measurement. For a proximal outer tube portion of 101.6-152.4 cm (32-60 inches) in length the pick count desirably will increase from a low of 11.8-17.7 picks per cm (30-45 picks per inch) at the proximal end of the proximal portion to a high of 45.3-59.1 picks per cm (115-150 picks per inch) at the distal end thereof.

The composite proximal outer tube section is suitably manufactured by casting first layers of polyimide from solution over a mandrel, weaving the stainless steel braid over the polyimide first layers and then overcoating the braid with second polymer layers cast from solution. The second polymer layers will typically also be polyimide. However, to further increase the flexibility of the proximal portion at its distal end, other more flexible polymers, such as polytetrafluoroethylene, may also be used in the second polymer layers.

Table I illustrates the effect of pick count variation on the stiffness of two proximal shaft portions of differing lengths and differing inner diameter (ID) and outer diameter (OD). Measurements were taken in English units. The polymer matrix first layers were polyimide and second layers were polytetrafluoroethylene.

TABLE I

	Distance from proximal end cm (inches)	ID mm (inches)	OD mm (inches)	Picks per cm (per inch)	Stiffness* gm/cm (lbs/in)	E MPa (psi)	Kink dia. cm (inches)
5	Proximal Shaft Portion A - 132.1 cm (52 inch) length						
	5.1 (2)	.757 (.0298)	.965 (.0380)	14.2 (36)	117.7 (.6590)	2974.8 (431460)	3.17 (1.25)
	20.3 (8)	.757 (.0298)	.965 (.0380)	17.3 (44)	118.0 (.6609)	2983.1 (432662)	3.17 (1.25)
10	35.6 (14)	.757 (.0298)	.968 (.0381)	18.1 (46)	82.3 (.4604)	2043.6 (296404)	2.54 (1.00)
	50.8 (20)	.759 (.0299)	.975 (.0384)	22.0 (56)	56.2 (.3145)	1338.3 (194110)	1.27 (.50)
15	66.0 (26)	.759 (.0299)	.978 (.0385)	22.8 (58)	42.8 (.2396)	1003.2 (145504)	1.02 (.40)
	81.3 (32)	.762 (.0300)	.978 (.0385)	26.8 (68)	37.7 (.2109)	890.0 (129085)	1.02 (.40)
	91.4 (36)	.765 (.0301)	.996 (.0392)	52.8 (134)	21.2 (.1190)	452.2 (65587)	.51 (.20)
20	111.8 (44)	.765 (.0301)	.996 (.0392)	56.7 (144)	23.1 (.1295)	492.0 (71355)	.51 (.20)
	127 (50)	.765 (.0301)	.993 (.0391)	53.5 (136)	26.0 (.1454)	561.3 (81406)	.51 (.20)
	Proximal Shaft Portion B - 106.7 cm (42 inch) length						
25	5.1 (2)	.879 (.0346)	1.069 (.0421)	13.8 (35)	129.3 (.7240)	2480.4 (359748)	3.81 (1.50)
	21.6 (8.5)	.881 (.0347)	1.077 (.0424)	15.0 (38)	112.9 (.6325)	2077.3 (301281)	2.54 (1.00)
30	38.1 (15)	.889 (.0350)	1.080 (.0425)	19.7 (50)	63.4 (.3552)	1179.7 (171101)	1.02 (.40)
	54.6 (21.5)	.889 (.0350)	1.085 (.0427)	22.8 (58)	56.9 (.3187)	1022.6 (148318)	1.02 (.40)
	71.1 (28)	.894 (.0352)	1.097 (.0432)	25.1 (64)	43.7 (.2450)	736.1 (106760)	.76 (.30)
35	87.6 (34.5)	.897 (.0353)	1.105 (.0435)	45.7 (116)	37.8 (.2116)	610.6 (88556)	.51 (.20)
	102.9 (40.5)	.897 (.0353)	1.105 (.0435)	56.7 (144)	40.3 (.2257)	651.4 (94475)	.51 (.20)

40 * cantilevered beam (one end fixed) concentrated load at free end, measured on 1.27 cm (0.5 inch) segment centered at specified distance from proximal end.

WHAT IS CLAIMED IS:

1. A dilatation catheter comprising:
 - an inflatable balloon; and
 - an outer tubular shaft having a proximal outer tube section and a distal
 - 5 outer tube section, the proximal outer tube section and the distal outer tube section each having proximal and distal ends, the proximal outer tube section having an irregular outer surface formed by a polymer matrix material conformingly encasing a tubular braid of a stainless steel member, the distal
 - 10 outer tube section formed of a polymeric material and having its proximal end connected to the distal end of the proximal outer tube section and its distal end connected to a proximal end of the balloon.
2. A dilatation catheter comprising:
 - an inflatable balloon;
 - 15 a composite polyimide/stainless steel braid proximal outer tube section having proximal and distal ends and a textured outer surface, the textured outer surface formed by polymer material conformingly encasing a tubular braid of a stainless steel member;
 - a polyethylene distal outer tube section having proximal and
 - 20 distal ends the proximal end thereof connected to the distal end of the proximal outer tube section, and the distal end connected to a proximal end of the inflatable balloon;
 - an inner tubular member which extends through the proximal and distal outer tube sections, the inner tubular member defining a
 - 25 guide wire lumen and having a distal end connected to a distal end of the inflatable balloon.
3. A dilatation catheter as in claim 1 or claim 2 wherein the proximal outer tube section has a wall thickness of about 0.064 mm (0.0025 inches) to about 0.102 mm
- 30 (0.0040 inches).

4. A dilatation catheter as in claim 3 wherein the proximal outer tube section has an outer diameter of between about 0.76 mm (0.030 inches) and about 1.32 mm (0.052 inches).

5 5. A dilatation catheter as in claim 1 or claim 2 wherein the stainless steel tubular braid is formed of multiple stands of a stainless steel ribbon.

6. A dilatation catheter as in claim 5 wherein the ribbon has a thickness of about 0.008 mm (0.0003 inches) to about 0.038 mm (0.0015 inches) and a width of
10 about 0.038 mm (0.0015 inches) to about 0.18 mm (0.007 inches).

7. A dilatation catheter as in claim 6 wherein the proximal outer tube section has a wall thickness at points of maximum thickness of about 0.064 mm (0.0025 inches) to about 0.102 mm (0.0040 inches).

15

8. A dilatation catheter as in claim 5 wherein multiple strands are woven together in a weave having about 17.7 to 35.4 picks per cm (45 to 90 picks per inch).

9. A dilatation catheter as in claim 1 further comprising:

20 an inner tube which extends through the outer tubular shaft, the inner tube defining a guide wire lumen and having a distal end which is connected to a distal end of the balloon.

10. A dilatation catheter as in claim 9 wherein the inner tube and the outer
25 tubular shaft define an inflation lumen between an outer surface of the inner tube and an inner surface of the outer tubular shaft.

11. A dilatation catheter as in claim 1 wherein the distal outer tube section is formed of polyethylene.

30

12. A dilatation catheter as in claim 1 or claim 2 wherein the distal outer tube section has a length of about 29.2 to 31.8 cm (11.5 to 12.5 inches).

13. A dilatation catheter as in claim 12 wherein the proximal outer tube section has a length of about 106.7 to 109.2 cm (42 to 43 inches).
14. A dilatation catheter as in claim 1 or claim 2 wherein the stiffness of the proximal outer tube section decreases from the proximal to the distal end thereof.
15. A dilatation catheter as in claim 14 wherein the stiffness of the proximal outer tube section is in the range of 110-130 gm/cm at the proximal end thereof and is in the range of 15-41 gm/cm at the distal end thereof using a 1.27 cm segment for measurement.
16. A dilatation catheter as in claim 1 or claim 2 wherein the stainless steel tubular braid is formed of multiple stands of stainless steel woven together in a weave having an increasing pick count moving from the proximal end to the distal end of the proximal outer tube section.
17. A dilatation catheter as in claim 16 wherein the proximal outer tube section has a length of 101.6-152.4 cm (32-60 inches), a pick count at the proximal end thereof of 11.8-17.7 picks per cm (30-45 picks per inch) and a pick count at the distal end thereof of 45.3-59.1 picks per cm (115-150 picks per inch).
18. A dilatation catheter as in claim 1 or claim 2 wherein the polymer matrix material is polyimide.
19. A dilatation catheter as in claim 1 or claim 2 wherein the polymer matrix material comprises a layer of polyimide under the tubular stainless steel braid and a second polymer layer of a more flexible polymer overcoating the braid.
20. A dilatation catheter as in claim 19 wherein the second polymer layer is polytetrafluoroethylene.
21. A dilatation catheter comprising:

a proximal outer tube having an outer surface bearing a texture of a polyimide-encased tubular braid of a stainless steel member contained therein, a wall of the proximal outer tube having a thickness ranging from about 0.064 mm (0.0025 inches) to about 0.102 mm (0.0040 inches);

5 a proximal inner tube extending through the proximal outer tube;

a distal outer tube formed of polyethylene and having a proximal end connected to a distal end of the proximal outer tube;

10 a distal inner tube having proximal and distal ends, and having an outer diameter which is less than an outer diameter of the proximal inner tube, the proximal end of the distal inner tube being connected to a distal end of the proximal inner tube;

an inflatable balloon having a proximal portion connected to the distal end of the distal outer tube, and having a distal portion connected to the distal end of the distal inner tube.

15

22. The dilatation catheter of claim 21 wherein the proximal inner tube extends through the proximal outer tube and into the distal outer tube.

23. The dilatation catheter of claim 21 wherein the proximal and distal inner
20 tubes are formed by a unitary polyethylene tube.

24. A balloon catheter for use with a guide wire, the balloon catheter comprising:

25 a shaft having a proximal section, a distal section, a proximal end, a distal end, and a lumen which extends between the proximal end and the distal end, the proximal section having an irregular outer surface formed by polyimide material conformingly encasing a tubular braid of a stainless steel member, and the distal outer tube section formed of a polymeric material and further connected to the proximal section;

30 a balloon carried at the distal end of the shaft, the balloon having an interior which is in fluid communication with the lumen to permit inflation and deflation of the balloon, wherein the balloon is longitudinally compliant so that it increases in length as it is inflated;

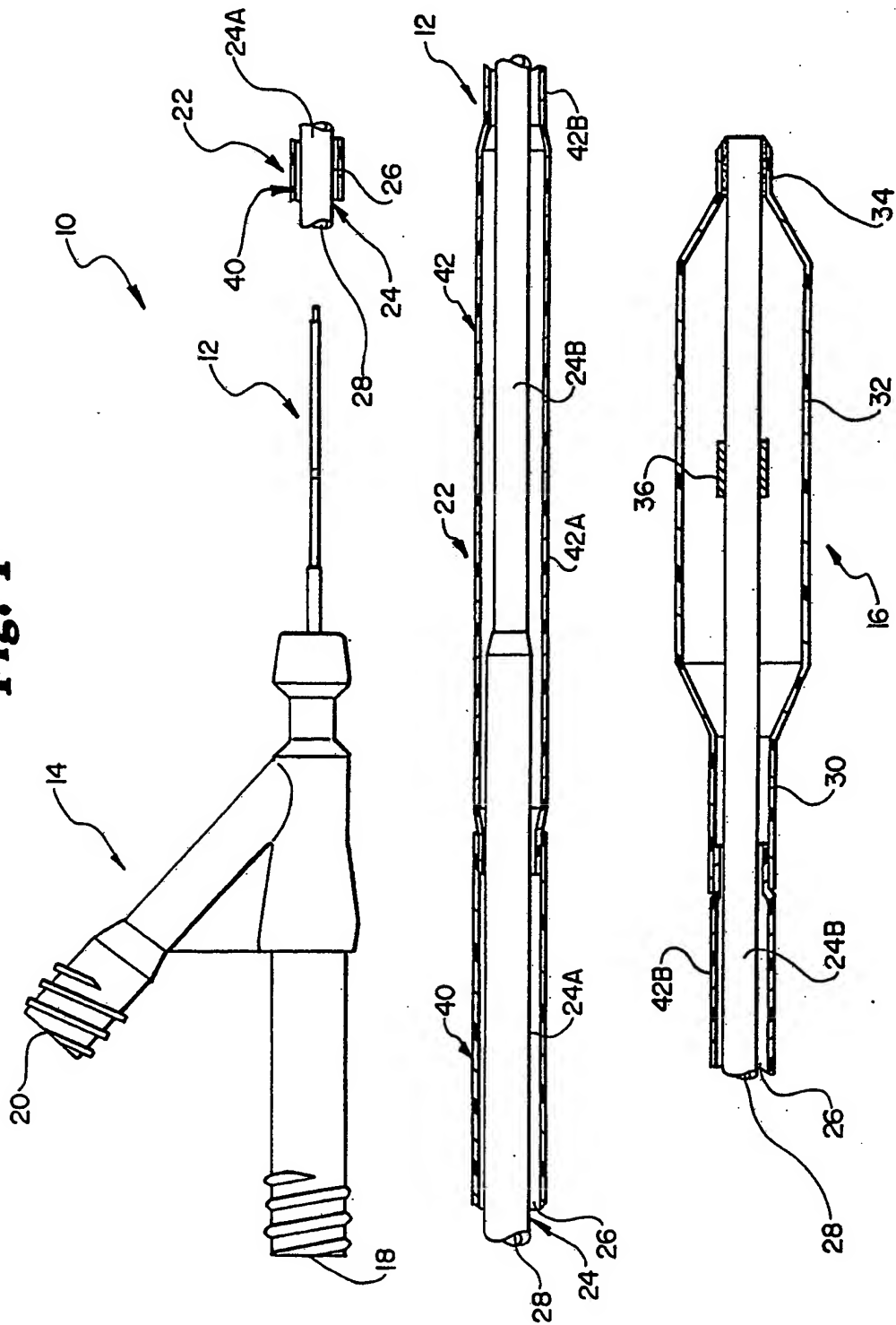
a lumen extension through the interior of the balloon, the lumen extension being connected to the lumen to provide a passage for the guide wire to extend through the shaft and the balloon, the lumen extension having an inner diameter which permits relative movement of the guide wire and the balloon catheter and which provides a resistance to fluid flow past the guide wire in the lumen extension which is greater than resistance to fluid flow between the lumen and the interior of the balloon; and

valve means responsive to elongation of the balloon for blocking fluid flow through the lumen extension when the length of the balloon is greater than a threshold value.

25. A catheter for insertion into the body comprising:

an outer tubular shaft having a proximal outer tube section having proximal and distal ends, the proximal outer tube section comprising a polymer encased tubular braid of stainless steel, the braid having a weave which increases in pick count from the proximal end to the distal end of the proximal outer tube section.

Fig. 1



1/4

SUBSTITUTE SHEET

Fig. 2

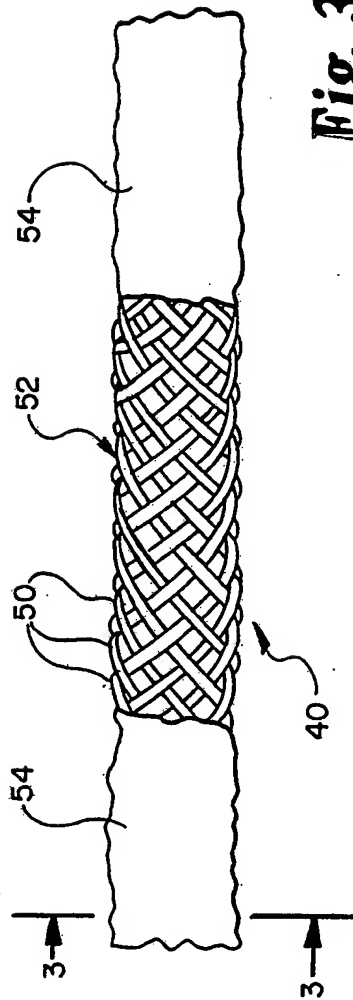


Fig. 3

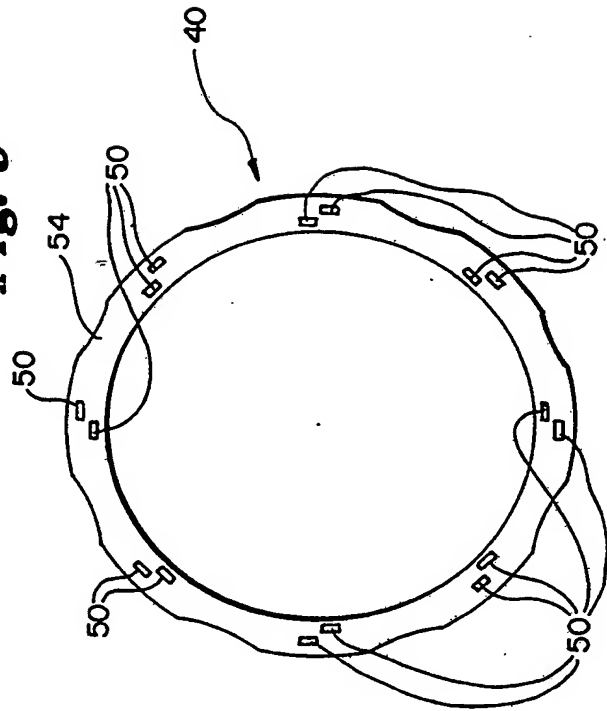


Fig. 4

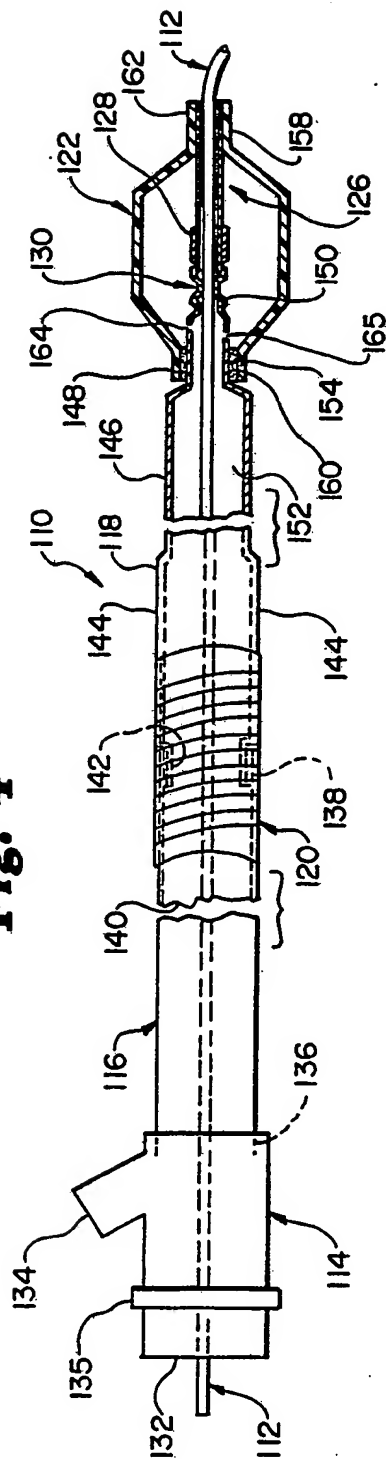


Fig. 5

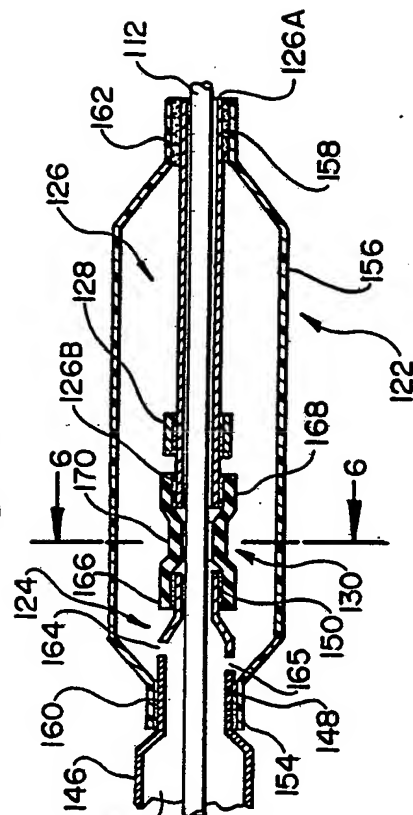


Fig. 6B

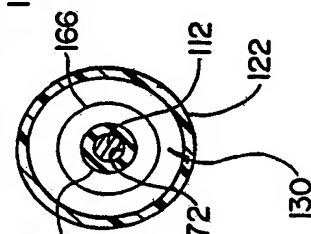


Fig. 6A

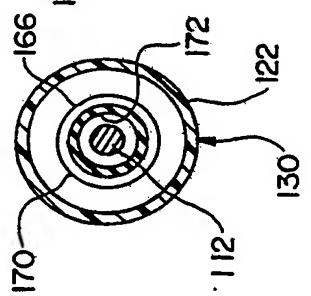
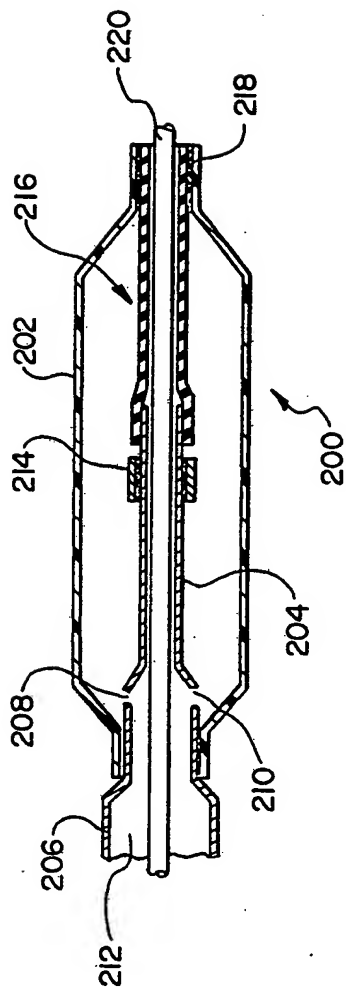


Fig. 7



I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ⁶		
According to International Patent Classification (IPC) or to both National Classification and IPC Int.Cl. 5 A61M29/02		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁷		
Classification System	Classification Symbols	
Int.Cl. 5	A61M	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁸		
III. DOCUMENTS CONSIDERED TO BE RELEVANT⁹		
Category ^o	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
Y	EP,A,0 249 338 (C.R. BARD, INC.) 16 December 1987 see column 8, line 5 - line 44; figures 1-2,5-9 <div style="text-align: center;">---</div>	1,9-10, 14,20-23
Y	WO,A,9 001 406 (BURNHAM) 22 February 1990 see page 18, last paragraph; figures 4-7 <div style="text-align: center;">---</div>	1,9-10, 14,20-23
A	EP,A,0 358 117 (ADVANCED CARDIOVASCULAR SYSTEMS, INC.) 14 March 1990 see page 4, line 32 - line 51; figures <div style="text-align: center;">---</div>	1-25
A	EP,A,0 428 976 (SCIMED LIFE SYSTEMS, INC.) 29 May 1991 see column 4, line 13 - column 9, line 21; figures <div style="text-align: center;">---</div> <div style="text-align: right;">-/--</div>	1-25
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>^o Special categories of cited documents: ¹⁰</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"I" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 45%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&" document member of the same patent family</p> </div> </div>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search <div style="text-align: center;">09 JULY 1993</div>		Date of Mailing of this International Search Report <div style="text-align: center;">13. 08.93</div>
International Searching Authority <div style="text-align: center;">EUROPEAN PATENT OFFICE</div>		Signature of Authorized Officer <div style="text-align: center;">MIR Y GUILLEN V.</div>

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)		
Category ^a	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.
A	<p>WO, A, 8 700 442 (A/S MEADOX SURGIMED) 29 January 1987 see abstract; figures 3-5 -----</p>	1-25

**ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO.**

US 9303352
SA 73027

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information. 09/07/93

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP-A-0249338	16-12-87	AU-A- 7413387 JP-A- 62298373	17-12-87 25-12-87
WO-A-9001406	22-02-90	US-A- 4764324 EP-A- 0380543	16-08-88 08-08-90
EP-A-0358117	14-03-90	US-A- 4981478 JP-A- 2191465 US-A- 5176661	01-01-91 27-07-90 05-01-93
EP-A-0428976	29-05-91	US-A- 5047045 CA-A- 2029489 JP-A- 3207376	10-09-91 14-05-91 10-09-91
WO-A-8700442	29-01-87	US-A- 4706670 EP-A,B 0240504 JP-T- 63500289	17-11-87 14-10-87 04-02-88

EPO FORM P0579

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82